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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,364	06/21/2003	Iris Ginron Zhao		7109

7590 05/13/2008

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,364	ZHAO, IRIS GINRON	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-16 were cancelled by Applicants. Claims 17-30 are now pending for examination.

Priority

2. As stated in the prior Office Action, this instant application is granted priority to prior application 09/589248. The filing date of 09/589248 Application is June 07, 2000.

Drawings

3. The drawings were received on 11/16/2007. These drawings are acceptable.

Response to Arguments

4. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection over new claims 17-30.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the phrase "A method of making an artificial comprising.." This phrase is vague and indefinite since it is unclear what the term "artificial" is intended to encompass within the context of this claim.

7. Claims 18-25 recite the phrase "the artificial graft according to claim 17." There is insufficient antecedent basis for this limitation in claim 17.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 25 recites the broad recitation "endothelium growth factor," and the claim also recites "endothelium growth hormone" and "endothelial cell growth factor," which are the narrower statements of the range/limitation.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Instant claim 24 comprises within its scope an "embryo." The scope of this term encompasses a human embryo, which is non-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 102

11. Claims 17, 19-22, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim et al. (US Patent No. 3,774,615).

12. **It is noted here that although Applicant argues that the instant invention differs from the prior art to the extent that the claimed methods comprise *in situ* vein formation, the method of claim 17 does not require *in situ* vein formation. Only claim 18, requires a step wherein a vessel graft is formed *in situ*.

13. Therefore, claim 17, 19-22, and 24-25 are rejected over Lim et al. which describe a device for connecting the ends of interrupted tubular organs, comprising a connecting ring over which the ends of the interrupted organs are pulled. The ring and fastening means are preferably a hydrophilic gel, which may be swollen to equilibrium or which may be an incompletely swollen hydrogel, which is subjected to additional, swelling at the place of application. Moreover, Lim et al. recites: "[T]ests and experiments have been carried out with gels made from polymers of ethylene glycol lmonomethacrylate which were cross-linked with less than 10 percent of a cross-linking agent, such as, for example, ethylene glycoldimethacrylate, or their copolymers, such as, for example, diethylene glycolmethacrylate with methylmethacrylate, acrylonitrile, methacrylic acid, and the like. However it is also possible to use other physiologically inert hydrogels, for example polymeric N-alkyl methacrylamides, N-alkyl acrylamides, N,N-dialkyl acrylamides, and the like. These hydrogels may also contain suitable drugs which facilitate healing, such as, for example, antibiotics, *collagen,* globulin, and the like which

may be introduced into the polymer before and during polymerisation or even added after polymerization when the gel is in the swollen state." (see col. 6, lines 8-24).

14. Lim et al. is interpreted as reading on claims 21-22 to the extent that these claims appear to be limited to the adhesive material, not to the removable device.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombard et al. (US Patent Application Publication No. US 2001/0007069 A1, priority to July 28, 1999) in view of Murray et al. (US 2002/0123805).

17. Bombard et al. discloses methods comprising connecting a target vessel and the end of a graft vessel comprising the application of a tissue adhesive to the mating surfaces of the graft vessel and/or target vessel, and puncturing the adhesive comprising the use of a removable device, see paragraph [0017] of the disclosure of this publication, which teaches a method comprising applying a tissue adhesive to the mating surfaces of the graft vessel and/or target vessel, and inserting an elongated anvil through the wall of the target vessel and positioning the anvil along an interior of the target vessel wall; positioning the end of the graft vessel adjacent an exterior of the target vessel wall; and curing the adhesive. The adhesives useful in the methods of Bombard et al. may comprise materials such as fibrin and collagen and may be applied

as a liquid or solid, see paragraph [0073] of Bombard et al. which recites: "[I]n the case of adhesive bonding, the adhesive can be applied to the tissue mating surfaces of the graft and/or target vessels before the surfaces are brought into contact. The adhesive may be applied to either or both of the mating surfaces of the graft and target vessels. The adhesive may be a one part or a two part adhesive. Further, the curing of the adhesive may be activated by light or heat energy. The adhesive may be applied as a liquid or as a solid film. Preferred adhesive materials include collagen, albumin, fibrin, hydrogel and glutaraldehyde. Other adhesives such as cyano-acrylates may also be used.

18. However, Bombard et al. does not teach the formation of an artificial graft comprising the *in situ* vessel formation.

19. Murray et al. (US 2002/0123805) discloses tissue adhesive compositions comprising collagen, an extra-cellular matrix protein, and a platelet. The invention further provides a composition of collagen, a platelet and a neutralizing agent, e.g. sodium hydroxide or hydrochloric acid. The method further comprises contacting the ends of an injured tissue from a patient with the compositions of this invention. The compositions can additionally include plasma, wherein the plasma is derived from the patient it is administered to, in other aspects the plasma is derived from a donor that is allogeneic to the patient (reads on claim 23). The compositions may include one or more additives, such as the following:

[0010] Alternatively, the composition includes one or more additives, such as insoluble collagen, a growth factor, a cross-linking agent, a stem cell, a genetically altered fibroblast and a cell media supplement. Growth factor include for example, platelet derived growth factor-AA (PDGP-AA), platelet derived growth factor-BB (PDGF-BB), platelet derived growth factor-AB (PDGF-AB), transforming growth factor beta (TGF-β), epidermal growth factor (EGF), acidic fibroblast growth factor (aFGF), basic fibroblast growth factor (bFGF), insulin-like growth factor-1 (IGF-1), interleukin-1-alpha (IL-1α), and insulin.

[0011] By cross-linking agent is meant that the agent is capable of forming chemical binds between the constituents of the composition. The cross-linking agent can be example, a protein or a small molecule, e.g., glutaraldehyde or alcohol.

[0012] Cell media supplement is meant to include for example glucose, ascorbic acid, antibiotics, or glutamine.

20. This passage reads on claim 24 to the extent that it discloses an adhesive composition comprising collagen, and a stem cell; this passage reads on claim 25 to the extent that the compositions of Murray et al. may comprise TGF-beta, FGF, PDGF, and/or glucose. (In the reply filed 10-19-07, Applicants did not address the merits of the rejection of claims over Murray et al.).

21. It would have been obvious to the ordinary skilled artisan to modify the teachings of Bombard et al. by substituting the tissue adhesive compositions used in their methods with the functionally equivalent tissue adhesive compositions of the invention of Murray et al. In regards to the *in situ* vessel formation, absent evidence to the contrary, since the adhesive materials of Murray et al. may comprise the same essential elements as Applicant's adhesive materials, including plasma from a patient to be treated (i.e. a blood component from a patient to be treated), various growth factors

(such as PDGFs, TGF-beta, EGF, FGF, and IGF-1), collagen, a stem cell, and genetically altered fibroblast cells (*inter alia),* one of ordinary skill in the art would have expected that the compositions disclosed in Murray et al. would have the same properties as Applicant's adhesive materials, namely being capable of *in situ* vessel formation.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

/JLE/